



AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS®

Pharmacists in health systems helping people make the best use of medications

March 19, 1999

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Dockets Management Branch (HFD-210)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

**Re: Docket No. 98N-1265 -- Draft Federal/State Memorandum of Understanding on
Interstate Distribution of Compounded Drug Products**

To Whom It May Concern:

The American Society of Health-System Pharmacists (ASHP) is pleased to provide comments to the FDA on the January 21, 1999, *Federal Register* notice and request for comments on the draft standard Memorandum of Understanding (MOU) on interstate distribution of compounded drug products. ASHP is the 30,000-member national professional association that represents pharmacists who practice in hospitals, health maintenance organizations, long-term care facilities, home care agencies, and other components of health care systems.

In general, ASHP agrees with those portions of the draft MOU that address the interstate distribution of inordinate amounts of compounded drug products (Section III(C) of the MOU, pages 12-14). Our members have not commented adversely regarding section III(C)(1)(a) of the MOU.

The organization and wording of the section of the MOU (III(B), pages 5-12) that deals with the investigation of complaints about compounded drugs are troublesome. The new section 503A(b)(3)(B) of the Federal Food, Drug, and Cosmetic Act states that the MOU must provide "for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such State." However, the subheading for section III(B) on page 5 of the MOU is simply "Complaints About Compounded Drugs," and the explanation that the MOU authorizes one state to investigate complaints "*relating to compounded drug products distributed outside such State*" does not appear in section III(B) until page 9, well after the delineation of the specific types of complaints that should be investigated. This could cause some misunderstanding among those who might think that this section of the MOU deals with investigations complaints about intrastate, rather than interstate, distribution of compounded products.

98N-1265

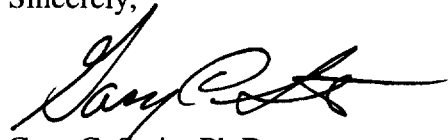
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A simple way to rectify this problem would be to change the title of subsection III(B) of the MOU "Complaints About Compounded Drug Products Dispensed or Distributed Interstate."

ASHP appreciates the opportunity to comment on the draft Memorandum of Understanding on Interstate Distribution of Compounded Drug Products. Feel free to contact me if you have any questions regarding our comments.

Sincerely,

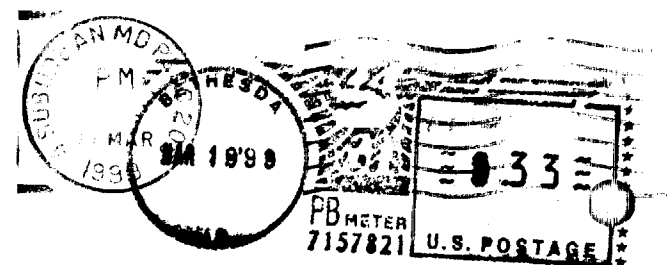
A handwritten signature in black ink, appearing to read "Gary C. Stein". The signature is fluid and cursive, with a large initial "G" and "S".

Gary C. Stein, Ph.D.
Director, Federal Regulatory Affairs

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AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS®
7272 WISCONSIN AVENUE ■ BETHESDA, MD 20814



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